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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,525	01/13/2004	Nady E. Nady	5032-104 US	2340
7590 12/29/2004			EXAMINER	
Gregory C. Houghton, Esq. Mathews, Collins, Shepherd & McKay, P.A. 100 Thanet Circle, Suite 306 Princeton, NJ 08540			COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,525

Applicant(s)

NADY, NADY E.

Examiner

David Comstock

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: page 2, line 7 (as numbered by Applicant), "The connection between the cross arms permits...a predetermined longitudinal relative shifting of said cross arms" is objected to because it is unclear from this statement alone and from the drawings, as submitted, how a pivotal connection can accomplish "longitudinal relative shifting of the cross arms."

Appropriate correction is required. Applicant is reminded that no new matter can be added.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claims 1, 12 and 23, "and a predetermined longitudinal relative shifting of said cross arms" has not been adequately described or explained in the specification in such a way as to convey the additional structure, or structural relationships, required, beyond the pivotal connection, which would be necessary to accomplish this.

Art Unit: 3732

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12 and 23, are not only not enabled as set forth above under 35 USC 112, first paragraph, but also, the manner in which applicant attempts to describe the function to be performed is vague and unclear. The specific structure or structural relationships which allow "predetermined longitudinal relative shifting of the cross arms" has not been adequately set forth. For examination purposes, and as best understood, these claims have been treated as disclosing at least a pivotal relationship as set forth therein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11-17 and 22-26, as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Weiss (5,868,668).

Weiss discloses a surgical retractor 10 comprising pivotally connected cross arms 35, 13 with a plurality of blades 28, 36 and rearward end portions with hand grips 54, 11 (see Figs. 1 and 4). The connection between the cross arms permits both

Art Unit: 3732

pivoting motion and longitudinal motion to lock the blades relative to each other (see, e.g., Figs. 4-6). Additional devices such as illumination and suction devices may be removably attached to a clip 48, 50 of a cross arm (see Fig. 1 and col. 4, lines 26-30).

The device is capable of being reused (that the device may be made with removable disposable blades to reduce contamination risk does not preclude the inherent capability of the tool to be sterilized and reused in the ordinary manner of surgical instruments). The device is used in a procedure to dilate a vaginal cavity wherein the device is inserted into the vaginal cavity and then the blades of the device are spread and locked open (see Fig. 14 and col. 4, lines 5-30). Furthermore, it is implicit that the additional components disclosed, including the illumination and suction means, are optionally used in the procedure (id.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7 and 18, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (5,868,668) in view of Francis et al. (5,072,720).

Weiss discloses the claimed invention except for the incrementally adjustable locking device.

Francis et al. disclose a similar device having an incrementally adjustable locking device 26, 40 to lock the device open in a smooth and convenient manner and allow a physician to use both hands, if needed, for the examination and/or treatment of the patient (see, e.g., Figs 1 and 2; col. 1, lines 36-38, 46-48 and 55-61; col. 3, lines 6-10; and col. 4, lines 32-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retractor of Weiss with an incrementally adjustable locking device, in view of Francis et al., in order to lock the device open in a smooth and convenient manner and allow a physician to use both hands, if needed, for the examination and/or treatment of the patient. Moreover, it is noted that to make the lock of Weiss adjustable would have also been obvious since it has been held that the provision of adjustability, where needed, involves only routine skill in the art. *In re Stevens*, 101 USPQ 284 (CCPA 1954).

Claims 8, 10, 19 and 21, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (5,868,668).

Weiss discloses the claimed invention except for the blades being formed of a flexible, elastomeric material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the blades of a flexible elastomer, or of any of numerous other known materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (5,868,668), as modified above with respect to claim 8, and further in view of Nwawka (6,036,638).

Weiss, as modified, discloses the claimed invention except for the elastomeric membrane. Nwawka discloses a similar device having an elastomeric membrane connecting the arms in order to improve the physician's visibility during a gynecological examination and to protect the vaginal region from pinching due to moving parts (see Fig. 4; Abstract; col. 1, lines 5-23; and col. 3, lines 32-42, 54-56 and 60-62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retractor of Weiss as modified, with an elastomeric membrane connecting the blades, in view of Nwawka, in order to improve the physician's visibility during a gynecological examination and to protect the vaginal region from pinching due to moving parts.

Claim 20, as best understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (5,868,668) in view of Nwawka (6,036,638).

Weiss discloses the claimed invention except for the elastomeric membrane. Nwawka discloses a similar device having an elastomeric membrane connecting the arms in order to improve the physician's visibility during a gynecological examination and to protect the vaginal region from pinching due to moving parts (see Fig. 4; Abstract; col. 1, lines 5-23; and col. 3, lines 32-42, 54-56 and 60-62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retractor of Weiss with an elastomeric membrane connecting the blades,

Art Unit: 3732

in view of Nwawka, in order to to improve the physician's visibility during a gynecological examination and to protect the vaginal region from pinching due to moving parts.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.



D. Comstock
26 December 2004



Cary E. O'Connor
Primary Examiner